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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,114	04/07/99	SAKAGUCHI S	07898/038001

HM22/0112

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EXAMINER	
MAYO,K	
ART UNIT	**PAPER NUMBER**
1633	3

DATE MAILED: 01/12/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary	Application No. 09/284,114	Applicant(s) Sakaguchi
	Examiner Kris Pelham Mayo	Group Art Unit 1633

☐ Responsive to communication(s) filed on _____.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☒ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☒ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☒ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: *Translation of Foreign Application* _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Priority

Acknowledgment is made of Applicant's claim for priority to PCT JP97/03591, filed on 10/07/1997.

Acknowledgment is made of Applicant's claim for priority to foreign application Japan 267126/1996, filed on 10/08/1996.

Although not required, it is recommended for clarification purposes that reference to the claims for priority be made in the first line of the specification.

Drawings

The drawings submitted with the instant application have been reviewed by the PTO Draftsperson and have been approved.

Specification

The specification is objected to because the Brief Description of the Drawings has been erroneously placed after the Detailed Description of the Invention.

The following guidelines illustrate the preferred layout and content for patent applications. These guidelines are suggested for the applicant's use.

Arrangement of the Specification

The following order or arrangement is preferred in framing the specification and, except for the reference to "Microfiche Appendix" and the drawings, each of the lettered items should appear in upper case, without underlining or bold type, as section headings. If no text follows the section heading, the phrase "Not Applicable" should follow the section heading:

(a) Title of the Invention.
(b) Cross-References to Related Applications.
(c) Statement Regarding Federally Sponsored Research or Development.
(d) Reference to a "Microfiche Appendix" (see 37 CFR 1.96).
(e) Background of the Invention.
    1. Field of the Invention.
    2. Description of the Related Art including information disclosed under 37 CFR 1.97 and 1.98.
(f) Brief Summary of the Invention.
(g) Brief Description of the Several Views of the Drawing(s).
(h) Detailed Description of the Invention.
(i) Claim or Claims (commencing on a separate sheet).
(j) Abstract of the Disclosure (commencing on a separate sheet).
(k) Drawings.
(l) Sequence Listing (see 37 CFR 1.821-1.825).

Deposit Requirement

Every patent must contain a written description of the invention sufficient to enable a person skilled in the art to which the invention pertains to make and use the invention. Where the invention involves a biological material, and words alone cannot sufficiently describe how to make and use the invention in a reproducible manner, access to the biological material is necessary for the satisfaction of the statutory requirements for patentability under 35 U.S.C. 112. See MPEP 2402-2411 and 37CFR 1.801-1.809. Because the claimed invention is a particular strain of mouse (biological material), and it may not be made in a reproducible manner (the mouse strain of

the invention appears to have been derived, through selective breeding, from a single mouse of another strain that exhibited an unusual phenotypic characteristic, and probably the result of a genetic mutation). While Applicant refers to the distribution of the SKG strain of mouse in accordance with Japanese Patent Law Enforcement Regulations on page 4 of the specification, this is insufficient assurance that all of the conditions of 37 CFR 1.801-1.809 have been met.

If the deposit was made under the provisions of the Budapest Treaty, filing of an affidavit or declaration by Applicant, Assignee, or a statement by an attorney of record over his or her signature and registration number stating that the deposit has been accepted by an International Depository Authority under the provisions of the Budapest Treaty, that all restrictions upon public access to the deposit will be irrevocably removed upon the grant of a patent on this application and that the deposit will be replaced if viable samples cannot be dispensed by the depository, is required. This requirement is necessary when a deposit is made under the provisions of the Budapest Treaty, as the Treaty leaves this specific matter to the discretion of each State. Amendment of the specification to recite the date of the deposit and the complete name and address of the depository is required.

Furthermore, unless deposit was made at or before the time of filing, a declaration filed under 37 CFR 1.132 is necessary to construct a chain of custody. The declaration, executed by a person in a position to know, should identify the deposited material by its depository accession number, establish that the deposited material is the same as that described in the specification, and

establish that the deposited material was in Applicant's possession at the time of filing. See In re Lundak, 27 USPQ 90.

If the deposit has not been made under the Budapest Treaty, then in order to certify that the deposit meets the criteria set forth in 37 CFR 1.801-1.809, Applicant may provide assurance of compliance by an affidavit or declaration, or by a statement by an attorney of record over his or her signature and registration number, showing that:

a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

c) the deposit will be maintained in a public depository for a period of 30 years, or 5 years after the last request, or for the enforceable life of the patent, whichever is longer;

d) a test of the viability of the biological material at the time of the deposit was made, and that the test results indicated that said biological material was viable (see 37 CFR 1.807); and,

e) the deposit will be replaced it should ever become inviable.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claim 1 is rejected under 35 U.S.C. 101 as unpatentable because the claimed invention is directed to non-statutory subject matter. The claims are anticipated by a naturally occurring article which has been deemed as non-statutory, non-patentable subject matter (MPEP 706.03 (a) and 2105). While the Patent and Trademark Office does consider nonnaturally occurring, nonhuman multicellular living organisms, including animals, to be patentable subject matter, it has to be made within the scope of 35 U.S.C. 101. A thing occurring in nature, which is substantially unaltered, is not a "manufacture". See MPEP 706.03(a). In the instant application, the SKG mouse has not been altered by the hand of man in any way, and is a naturally occurring animal. Therefore, the strain of mouse of claim 1 is considered to be directed to non-statutory subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite in its recitation of "the character", "autoimmune arthritis", and "the character being derived from the SKG strain." "[t]he character" is vague and indefinite

because it is not clear if natural onset of autoimmune arthritis has only one character and the mouse strain possesses that character, or if natural onset of autoimmune arthritis has multiple characters, and the mouse strain of the invention possesses only one of those. Also, it is not clear what is actually meant by "having the character", or what is encompassed within the term "character". For example, it is not clear if the phrase means that the mouse of the invention develops specific pathophysiological manifestations of autoimmune arthritis. Claim 1 is further indefinite in its recitation of the limitation "the character" in the first line, because there is insufficient antecedent basis for this limitation in the claim. No prior reference to "a character" in the claim, therefore, it is not clear what character the phrase is referring to. In the absence of clarity, the meets and bounds of the claimed invention cannot be determined.

The term "autoimmune arthritis" is indefinite because it is not clear what is meant by the term. The specification appears to teach rheumatoid arthritis, which is only one type of autoimmune arthritis known in the art. For example, The Merck Veterinary Manual teaches rheumatoid arthritis and systemic lupus erythematosus as two examples of autoimmune arthritis in the dog (page 474). In the absence of clarity, the metes and bounds of the claimed invention cannot be determined.

The phrase, "the character being derived from the SKG strain", is indefinite because the specification appears to teach that the mouse strain of the invention is the SKG strain. It is unclear how the SKG strain can be derived from the SKG strain. The specification appears to teach on page 4, final paragraph, that the SKG mouse of the invention was derived, through

selective breeding, from the BALB/c mouse strain. In the absence of clarity, the metes and bounds of the claimed invention cannot be determined.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 1 is rejected under 35 U.S.C. 102(b) as being anticipated by Nakamura et al. (1991), Hang et al. (1982), Bouvet et al. (1990), and Nordling et al. (1992).

The claim is drawn to a mouse strain that develops a natural (spontaneous) onset of immune-mediated arthritis. Nakamura et al. teach male New Zealand Black/KN mice (NZB/KN mice) that develop a natural (spontaneous) onset of immune-mediated arthritis. Hang et al. teach MRL/1 mice which also develop a natural (spontaneous) onset of immune-mediated arthritis. Additionally, Bouvet et al. teach Biozzi mice which also develop a natural (spontaneous) onset of immune-mediated arthritis. Furthermore, Nordling et al. teach DBA/1 mice which also develop a natural (spontaneous) onset of immune-mediated arthritis. Therefore, the mice of Nakamura et al., Hang et al., Bouvet et al., and Nordling et al. meet the limitations of the claim.

Conclusion

No claim is allowed, for the reasons outlined above.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kris Pelham Mayo whose telephone number is (703) 306-5877. The examiner can normally be reached on Monday-Friday from 8:00 a.m. to 4:30 p.m. (Eastern Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, John LeGuyader, can be reached at (703)308-0447. The FAX phone number for group 1600 is (703)308-4242.

An inquiry of a general nature or relating to the status of the application should be directed to the group receptionist whose telephone number is (703)308-0196.

Kris Pelham Mayo, D.V.M.
Patent Examiner
Art Unit 1633
January 10, 2000

Karen M. Hauda
Karen M. Hauda
Patent Examiner